



UNITED STATES DEPARTMENT OF COMMERCE
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PM

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
09/633,111	08/04/00	CARLSSON	J 1614-0238P

002292 HM22/1003
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EXAMINER	
NGUYEN, B	
ART UNIT	PAPER NUMBER

1641

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DATE MAILED: 10/03/01

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary

Application No.

09/633,111

Applicant(s)

CARLSSON ET AL.

Examiner

Bao-Thuy L. Nguyen

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 20 July 2001.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-10 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-10 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 4 & 6.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

1. Upon further consideration, the election/restriction of claims 1-10 is hereby withdrawn. All claims are rejoined and will be examined.

Priority

2. Receipt is acknowledged of papers submitted under 35 U.S.C. 119(a)-(d), which papers have been placed of record in the file.

Specification

3. The abstract of the disclosure is objected to because it is not in proper format. Correction is required. See MPEP § 608.01(b).

Claim Rejections - 35 USC § 112

4. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

5. Claims 1-7 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 1 is vague and indefinite with respect to the recitation of "membrane type flow matrix" because it is unclear what type of matrix is being claimed. Is it a membrane or is it not a membrane?

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Claim 1, part f2c) is confusing with respect to the recitation of "the flow" because it lacks antecedent support.

Claim 2 is confusing because it is unclear how the separated components, presumably on or in the flow matrix, are further immobilized to the flow matrix.

Claim 7 is objected to under 37 CFR 1.75(c) as being in improper form because a multiple dependent claim cannot be dependent on another multiply dependent claim. See MPEP § 608.01(n). Claim 7 is also confusing because it is unclear when or when in the method is the membrane placed on a flat support.

Claim Rejections - 35 USC § 102

6. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

7. Claims 1-4, 8-10 are rejected under 35 U.S.C. 102(b) as being clearly anticipated by Filipi et al (US Patent No. 4,313,906).

Filipi et al disclose a thin layer chromatography plate comprising a first surface portion including a first composition suitable to perform thin layer partition chromatography in a first direction on plate, and a second surface portion including a second composition suitable to perform thin layer chromatography in a second direction on the plate (column 1, lines 52-63). Filipi et al disclose that these plates may be used to separate different types of materials such as sulfonamides, bile acids, pesticides, hydrocarbons and pharmaceuticals and their metabolites.

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(column 1, line 64 through column 2, line 2). The plates as disclosed may be used in all possible combinations of adsorptive chromatography, thin layer partition chromatography and reverse phase thin layer partition chromatography (column 2, lines 26-29). Filipi et al disclose suitable material for thin layer partition chromatography including cellulose, polyamide powder and silica gel with organic materials bonded to them such as ion exchange groups and polyglycol or polyether groups (column 2, lines 55-61). Filipi et al disclose that the plate is first developed by placing the plate in contact with a first solvent such that the first solvent transports the mixture across the first portion of the plate for at least partially separating the mixture into its components parts by a first thin layer chromatography. After this first thin layer chromatography has taken place, the plate is removed from contact with the first solvent and dried. The plate is then further developed by placing the plate in contact with a second solvent, such that the second solvent transports the partially separated mixture from the first surface portion of the plate onto and across the second surface portion of the plate for further separation of the mixture into its component parts by a second thin layer chromatography (column 3, lines 37-67). Filipi et al disclose that the first second chromatographic developments are in directions perpendicular to each other. The separated mixture of the sample can then be analyzed by any of the well-known methods in the art such as fluorescein (column 4, lines 30-38). Filipi et al disclose that before use, the plate is washed overnight in a tank containing chloroform-methanol (column 7, lines 29-32).

8. Claims 8-10 are rejected under 35 U.S.C. 102(b) as being clearly anticipated by Pristoupil (Chromatography Review. 12:109-125, 1970).

Pristoupil discloses the general trends in the development of chromatographic and electrophoretic techniques and specifically teaches the use of nitrocellulose membrane filters for

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use in chromatography and electrophoresis separation of proteins and nucleic acids (pages 109-110). Pristoupil disclose a chamber for membrane chromatography where chromatography in aqueous solutions is performed in a horizontal position (page 112, figure 1). The samples are applied on the test strip and after separation, proteins and nucleic acids are visualized by either the sandwich techniques or dyes. Pristoupil discloses that nitrocellulose membranes impregnated with a suitable antigen can be used for the rapid detection, saturation or quantitative determination of specific antibodies in micro amounts of materials (page 119).

Claim Rejections - 35 USC § 103

9. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

10. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

11. Claims 5-10 are rejected under 35 U.S.C. 103(a) as being unpatentable over Filipi et al in view of Pristoupil (Chromatography Review., 12:109-125, 1970).

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See the discussion of Filipi et al above. This reference differs from the invention in failing to teach the separation and detection of proteins.

Pristoupil discloses the general trends in the development of chromatographic and electrophoretic techniques and specifically teaches the use of nitrocellulose membrane filters for use in chromatography and electrophoresis separation of proteins and nucleic acids (pages 109-110). Pristoupil disclose a chamber for membrane chromatography where chromatography in aqueous solutions is performed in a horizontal position (page 112, figure 1). The samples are applied on the test strip and after separation, proteins and nucleic acids are visualized by either the sandwich techniques or dyes. Pristoupil discloses that nitrocellulose membranes impregnated with a suitable antigen can be used for the rapid detection, saturation or quantitative determination of specific antibodies in micro amounts of materials (page 119). Pristoupil discloses that after electrophoresis of human serum, the wet strip is transferred and placed horizontally in a humid chamber. Strips of antiserum are placed along the membrane from the start and after incubation, the precipitated proteins were stained and detection. Up to twelve to fifteen fractions could be detection at a time (page 121).

It would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the nitrocellulose coated plates of Filipi et al as taught by Pristoupil for detection of proteins and nucleic acid because Pristoupil disclose that nitrocellulose membranes are very suitable for the rapid and simple characterization and analysis of very small samples of biological material. Pristoupil also discloses the optimal conditions for such separation techniques thus giving ample evidence for an expectation of success in using the method and device as taught by Filipi et al as modified by Pristoupil.

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A skilled artisan would have had a reasonable expectation of success in using the method and device of Filipi et al to separate proteins such as taught by Pristoupil because Filipi et al teach that their device and method offer the advantages of a combination of separation techniques offering further separation of a sample into its components parts enabling visualization (column 6).

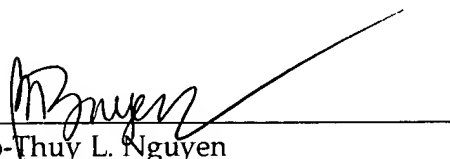
Conclusion

12. No claim is allowed.

13. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Bao-Thuy L. Nguyen whose telephone number is (703) 308-4243. The examiner can normally be reached on Monday, Wednesday and Thursday from 9:00 - 5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Long V. Le can be reached on (703) 305-3399. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 308-4242 for regular communications and (703) 308-3014 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.



Bao-Thuy L. Nguyen
Primary Examiner
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October 1, 2001